

REMARKS

The present invention relates to an isolated adipose tissue-derived stromal cell that exhibits at least one characteristic of a non-adipocyte cell lineage.

Claims 31-34 are currently pending. Claims 1-30 have been previously canceled. Claims 31-34 have been amended herein to more distinctly claim Applicants' invention. Moreover, claim 33 has been amended to indicate that the substance that promotes differentiation is selected from the group consisting of ascorbic acid, ascorbic 2-phosphate, bone morphogenetic proteins, β -glycerophosphate, or any combinations thereof. Support for the amendment to claim 33 is found throughout the as-filed specification (e.g. page 8, lines 1-30). As such, no new matter has been added by way of these amendments.

Rejection of claim 33 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 33 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner is of the opinion that claim 33 lacks antecedent basis. Accordingly, Applicants have amended claim 33 to recite "the cell of claim 32, wherein said substance that promotes differentiation is selected from the group..."

Applicants respectfully submit that the amendment to claim 32 is supported by the as-filed specification (e.g., see page 8, lines 1-30). No new matter has been added by way of this amendment. Applicants request reconsideration and withdrawal of the Examiner's rejection to claim 33 under 35 U.S.C. § 112, second paragraph.

Rejection of claims 31-34 pursuant to 35 U.S.C. § 112, first paragraph - written description

The Examiner has rejected claims 31-34 under 35 U.S.C. § 112, first paragraph for lacking written description. The Examiner contends that the specification does not support the broad interpretation of the claims because the specification does not sufficiently disclose a representative number of species for the claimed genus. Specifically, the Examiner asserts that the pending claims are not limited to a particular taxonomic species. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that they have indeed provided sufficient written description as required by the applicable law. In the landmark case of *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991), the Court of Appeals for the Federal Circuit

traced the development of the written description requirement under 35 U.S.C. §112, first paragraph. The *Vas-Cath* Court, in a unanimous opinion, noted approvingly that in a written description analysis, "[t]he primary concern is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Vas-Cath*, 19 USPQ2d at 1116 (quoting *In re Wertheim*, 191 USPQ 90, 96 (C.C.P.A. 1976)) (emphasis added). After discussing the policy reasons underlying the requirement, the Court set forth the standard for the written description requirement:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use;" the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. . . . The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas-Cath, 19 USPQ2d at 1117 (emphasis added) (quoting *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985)). Therefore, it is well-settled that the knowledge of those skilled in the art informs the written description inquiry.

In determining the sufficiency of support in a disclosure with respect to the written description requirement, "it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him." *In re Edwards*, 196 USPQ 465, 467 (C.C.P.A. 1978) (citing *In re Lukach*, 169 USPQ 795 (C.C.P.A. 1971); *In re Driscoll*, 195 USPQ 434 (C.C.P.A. 1977)). More recently, in *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983), the Court of Appeals for the Federal Circuit, citing *In re Edwards*, emphasized:

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. (Emphasis added).

In addition, in *In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996), the Court of Appeals for the Federal Circuit pointed out that literal support is not required in order to satisfy the written description requirement:

If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. For example, in *Ralston Purina Co. v. Far-Mor-Co., Inc.*, 227 USPQ 177, 180 (Fed. Cir. 1985), the trial court admitted expert testimony about known industry standards regarding temperature and pressure in "the art of both farinaceous and proteinaceous vegetable materials." The effect of the testimony was to expand the breadth of the actual written description since it was apparent that the inventor possessed such knowledge of industry standards of temperature and pressure at the time the original application was filed. (Emphasis added).

Therefore, it is clear that the invention need not be described in *ipsis verbis*, i.e., literally, for purposes of the written description requirement under 35 U.S.C. §112, first paragraph. Rather, what is needed is that the skilled artisan understand, based upon the disclosure in the specification as filed and the knowledge imputed to the skilled artisan at the time the specification was filed, that the inventor had possession of the claimed subject matter.

The Examiner is of the opinion that the specification as filed does not disclose a representative number of species or provide common structural components such that a skilled artisan would be able to identify members of the genus. Specifically, the Examiner contends that the claims are not limited to a particular taxonomic species and that the claims encompass at least cells that may or may not exist in other animals.

Applicants point out that the specification discloses the fact that adipose tissue-derived stromal cells are cells that originate from adipose tissue, where the adipose tissue may be from any organism having fat tissue. Preferably, the adipose tissue is from a mammal, most preferably the adipose tissue from human.

Throughout the specification, there is ample support for the claimed genus of an isolated adipose tissue-derived stromal cell. For example, an adipose stromal cell as encompassed in the pending claims is described beginning on page 8, line 24. In addition, the specification discloses that the stromal cells may be isolated from an organism of the same or different species to which the cells are transplanted into. Thus, one skill in the art would

appreciate that the cells can be autologous or allogeneic with respect to the recipient. The specification goes on to indicate that the source of adipose tissue or the method of isolation of adipose tissue is not critical to arriving at the cells of the invention. Thus, one skill in the art upon reading the specification would understand and appreciate that the cells of the invention can be isolated from fat tissue from any animal.

For the above reasons, Applicants contend that the specification amply supports an isolated adipose tissue-derived stromal cell generically. However, in order to expedite the prosecution of the present application, the claims have been amended to indicate that the cells are isolated from a mammal. Accordingly, Applicants respectfully submit that claims 31-34 as amended herein fully comply with the written description requirement set forth under 35 U.S.C. §112, first paragraph. As such, Applicants request that the rejection be reconsidered and withdrawn.

Rejection of claims 31 and 34 pursuant to 35 U.S.C. §101

The Examiner has rejected claims 31 and 34 under 35 U.S.C. § 101 because he contends that the claimed invention encompasses a cell as it occurs in nature and therefore is directed to non-statutory subject matter. Applicants disagree with the Examiner. Applicants point out to the Examiner that the claims recite an “isolated cell.” The specification teaches that the cells are isolated from adipose tissue and cultured *in vitro* prior to experimental and therapeutic use of the cells. Therefore, claims 31 and 34 properly complies with the requirements set forth under 35 U.S.C. § 101. Applicants request reconsideration and withdrawal of the Examiner’s rejection to claims 31 and 34 under 35 U.S.C. §101.

Double Patenting Rejection

The Examiner has rejected claims 31-34 as being in conflict with claims 1-6 of U.S. Patent No. 6,391,297 (“the ‘297 patent”) and claims 1-32 of U.S. Patent No. 6,429,013 (“the ‘013 patent”) under the judicially created doctrine of obviousness-type double patenting. Specifically, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct.

With respect to the ‘297 patent, Applicants understand that a timely filed Terminal Disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome such a

non-statutory type of double patenting rejection. Accordingly, Applicants are filing the appropriate Terminal Disclaimer herewith. Therefore, Applicants respectfully submit that the Double Patenting rejection with respect to the '297 patent has been overcome. However, with respect to the '013 patent, Applicants respectfully traverse the present Double Patenting rejection for the following reasons.

As an initial matter, it is understood that a double patenting rejection is based on a judicially created doctrine primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent. As such, Applicants do not understand the reasoning behind the Examiner's rejection to claims 31-34 as being in conflict with claims 1-32 of the '013 patent in view of the fact that the '013 patent would expire after the expiration date of any patent granted in connection with the present application. That is because the present application is a continuation of U.S. Application No. 09/554,868, filed May 19, 2000, now U.S. Patent 6,391,297, which is a §371 national phase application based on International Patent Application No. PCT/US98/25449, filed December 1, 1998, which claims priority to U.S. Provisional Patent Application No. 60/067,334, filed December 2, 1997. In essence, the instant application has an earlier priority date than the '013 patent. Therefore, the rejection of the claims based on the '013 patent is inapplicable.

In any event, any patent granted based on the instant application would expire before the '013 patent. Therefore, Applicants believe that the rejection of claims 31-34 as being in conflict with claims 1-32 of the '013 patent under the judicially created doctrine of obviousness-type double patenting is moot.

Summary:

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that claims 31-34 are in condition for allowance. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,

Halvorsen et al.

January 6, 2006
(Date)

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Enclosures: Terminal Disclaimer Transmittal Letter
Terminal Disclaimer under 37 C.F.R. § 1.321(c)